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| APPLICATION NO.                                               | FILING DATE | FIRST NAMED INVENTOR       | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------|-------------|----------------------------|---------------------|------------------|
| 09/869,229                                                    | 06/25/2001  | Richard Ian Christopherson | DAVII39.001A        | 2287             |
| 500                      7590                      01/08/2004 |             |                            |                     |                  |
| SEED INTELLECTUAL PROPERTY LAW GROUP PLLC                     |             |                            |                     |                  |
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| SEATTLE, WA 98104-7092                                        |             |                            |                     |                  |
| EXAMINER                                                      |             |                            |                     |                  |
| LY, CHEYNE D                                                  |             |                            |                     |                  |
| ART UNIT                                                      |             | PAPER NUMBER               |                     |                  |
| 1631                                                          |             |                            |                     |                  |

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/869,229

Applicant(s)

CHRISTOPHERSON ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on June 02, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-57 is/are pending in the application.
- 4a) Of the above claim(s) 15-29, 31-35, 47-52 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 36-46, 53, 54, 56, and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 and 31-57 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/03.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Applicants' arguments filed June 02, 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The addition of new claims 56 and 57 has been acknowledged.

#### **CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. This is a new matter rejection.

6. Claim 57 recites the limitations of antibodies or antibody parts bound to the array covalently or by first binding protein G to the array which is not disclosed in the instant specification and specifically on page 33, lines 10-13.

#### **CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 4 and 8 which directly or indirectly depend from claim 1 recite the limitation of an array is defined by the formula which causes the claims to be vague and indefinite because it is unclear whether said array is a mathematical representation of a rectangular arrangement of quantities in rows and columns; or a substrate for detecting biological interactions.

Clarification of the metes and bounds of the claims is required.

#### **CLAIM REJECTIONS - 35 USC § 102**

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4, 6-8, 14, 36-42, and 56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Clarkson et al. (1991).

12. Clarkson et al. discloses an ELISA device comprising phOx-BSA binding to phage from harvest supernatant comprising a combinatorial library of the rearranged heavy (VH) and kappa (Vk) light chains arranged in a matrix (array) from immunized mice (Abstract etc.). The binding is judged by the ELISA signal, seemed to vary (marked by shading); no binding was seen to BSA alone and wherein an interaction is indicative of a condition (page 626, Figure 2a and Methods §), as in instant claims 1-4, 6, 8, 14, 36, 37, 39- 42, and 56.

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13. The assay is performed in a 96-well plate and the phage supernatant is harvested from colonies of phage-transduced bacteria cells (page 626, Methods §), as in instant claim 7.

14. "The intensity of ELISA signals from the hierarchical libraries, corrected relative to the signal from control phage and at 405 nm 0.9-2.0 (++)" (page 626, Figure 2a), as in instant claim 38.

*Claim Rejections - 35 USC § 103*

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(e) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-14, 36-46, 53, 54, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarkson et al. (1991) taken with Marks et al. (1991) in view of Gallo et al. (US005968513A).

18. Clarkson et al. discloses the limitations of claims 1-4, 6-8, 14, 36-42, and 56 as cited above.

19. However, Clarkson et al. does not disclose the limitation of labeled antibody as recited in claims 53 and 54.

20. Marks et al. discloses the treatment of bacterial and viral infections with antibodies wherein the peroxidase labeled antibodies detect ~~the~~ the binding of  $\alpha$ TEL9 to lysozyme (column 587, column 2, lines 5-8), as in instant claims 53 and 54.

21. However, Clarkson et al. and Marks et al. do not disclose the limitations of claims 5, 9-13, and 43-46.

22. Gallo et al. discloses a treatment for cancer and certain immunological disorders (column 2, lines 22-25) such as diabetes type I (Table 1, § IV), as in instant claims 5 and 43.

23. The method of Gallo et al. uses monoclonal antibodies, which recognize cell surface determinants (antigen) in fluorescence-activated cells sorting procedures (column 16, lines 13-17). Further, the use of antibodies to isolated stem and progenitor cells (column 16, lines 9-13) capable of proliferating and differentiating along a myeloid differentiation pathway (column 1, lines 57-60), as in instant claims 9 and 10.

24. The pathogens cause infections which may be treated with recombinant stem cells according to this embodiment of the invention include but are not limited to lymphotropic viruses such as HIV, gram-negative bacilli such as Brucella or Listeria; the mycobacterium which cause tuberculosis or which cause Hansen's disease (leprosy); parasites such as Plasmodium (the etiological agents of malaria), or Leishmania; and fungi (such as those that

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cause pneumonia and other lethal infections secondary to immunodeficiencies)" (Column 13, lines 43-52), as in claims 11-13 and 44-46.

25. Marks et al. discloses a general method of treatment (page 581, lines 1-4) using antibodies by improving the chemical library production and improving the selection of higher affinity antibodies for said treatments (page 595, column 2, lines 9-16). Clarkson et al. discloses a method of generating antibodies with greater diversity and strong binding activities (Abstract etc.). Gallo et al. discloses a method of treatment for diseases caused by pathogens (Column 13, lines 43-52). The improvements for the general method of treatment by Marks et al. is directly applicable to the method Clarkson et al. and Gallo et al.

26. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvements disclosed by Marks et al. and improve on the method of treatment of diseases caused by pathogens as taught by Gallo et al. by using antibodies with greater diversity and strong binding activities as taught by Clark et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of treating diseases with an a diverse set of antibodies which have higher binding activities as taught by Marks et al., Clarkson et al. and Gallo et al.

### CONCLUSION

27. NO CLAIM IS ALLOWED.

28. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall I. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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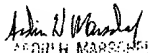
(November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

31. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
11/21/03

  
ANDREW H. MARSDEN  
Examiner